I. Remarks

Status of Claims

Claims 49-50 have been added to further expand the claimed embodiments of the elected subject matter. New claims 49-50 find support in the claims as originally filed and throughout the specification. Specifically, support for new claims 49-50 can be found, for example, at page 300, paragraph 868, through page 301, paragraph 871 (Method of identifying an antibody that specifically binds a polypeptide). Accordingly, no new matter has been added. Upon entry of the present amendment, claims 25-50 will be pending.

II. *Rejections of claims 25-48 under 35 U.S.C. § 112*

Rejection of claims 25-48 for alleged lack of written description

The Patent Office rejected claims 25-48 under 35 U.S.C. § 112, first paragraph because the specification allegedly lacks written description of the claimed invention. *See*, Paper No. 20060519, page 2, comment 5. More specifically, the Patent Office has alleged that the location in the specification where Applicants drew support for amendments made to claims 25, 37, and 48 only discloses the "use of polypeptide[sic] for detecting or treating cancer and not antibody[sic] as claimed." Applicants respectfully disagree and traverse this rejection.

Applicants respectfully direct the Patent Office to page 13, paragraph 32, last sentence, of the specification where it states: "Protein, as well as, antibodies directed against the protein may show utility as a tumor marker and/or immunotherapy targets for the above listed tissues." (emphasis added). Furthermore, Applicants respectfully direct the Patent Office to original claim 13 filed with the specification on December 12, 2003 that reads "An isolated antibody that binds specifically to the isolated polypeptide of claim 11," where original claim 11(b), also filed with the specification on December 12, 2003, reads: "An isolated polypeptide comprising an amino acid sequence at least 95% identical to a sequence selected from the group consisting of: a polypeptide fragment of SEQ ID NO:Y or the encoded sequence included in ATCC Deposit No:Z, having biological activity."

Accordingly, Applicants respectfully submit that the specification and the original claims as filed provide support for the use of an antibody to detect or treat cancer and therefore respectfully request that the Patent Office's rejection for alleged lack of written description under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

Rejection of claims 25-48 for alleged lack of enablement

The Patent Office rejected claims 25-48 under 35 U.S.C. § 112, first paragraph because the specification allegedly does not describe the subject matter of the invention in such a way as to enable one of skill in the art to make and/or use the invention. *See*, Paper No. 20060519, pages 2-4, comment 6. More specifically, the Patent Office has alleged that one of skill in the art would require undue experimentation to practice the claimed invention because: (1) it is unclear how one antibody can detect and treat all cancers; (2) the lack of working examples in the specification relating to the use of an antibody to the protein encoded by SEQ ID NO:35 in diagnosing or treating cancer; and (3) the specification does not disclose any particular disease condition that the claimed antibody detects. *See*, Paper No. 20060519, pages 3-4, comment 6. Applicants respectfully disagree and traverse this rejection.

Applicants respectfully submit that claims 25, 37 and 48 recite "wherein said antibody or fragment thereof is useful for detecting or treating cancer." In addition, the specification describes the invention as "useful for treatment, detection, diagnosis and/or prevention of cancer, particularly brain, bladder, ovarian or skin cancer, squamous carcinoma, renal cell carcinoma or squamous cell oesophageal carcinoma. Representative uses are described in the "Regeneration" and "Hyperproliferative Disorders" sections below, in Example 11, 15, and 18, and elsewhere herein." Paragraph 32, pages 11-12.

As a result, one of skill in the art would understand that the claimed antibody is useful for treatment or diagnosis of the cancers and hyperproliferative disorders disclosed in the specification, and contrary to the Patent Office's assertions, would not expect the claimed antibody to detect or treat all cancers. In this way, the specification discloses specific cancers and hyperproliferative disorders amenable to detection or treatment using the claimed antibody. *See*, Paragraph 32, pages 11-12. Finally, Applicants respectfully submit that the examples and disclosure of the instant specification would inform one of skill in the art how to use the claimed antibody in diagnosing or treating cancer without undue experimentation. In particular, Applicants respectfully submit that, *inter alia*, Examples 10, 22, 23, 25, 31, 53-55, 58, and paragraphs 507-512, pages 188-190, teach one of skill in the art how to use the claimed antibodies in the diagnosis or treatment of cancer.

Thus, Applicants respectfully submit that one of skill in the art, informed with the teachings of the instant specification, would be able to make and/or use the claimed invention. Accordingly, Applicants respectfully request that the Patent Office's rejection for alleged lack of enablement under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

III. ***Rejections of claims 25-48 under 35 U.S.C. § 103(a)***

The Patent Office rejected claims 25-48 under 35 U.S.C. § 103(a) as being allegedly unpatenable over EMBL accession number AL035289 in view of Campell (ed.), Monoclonal Antibody Technology, 1985; 2nd Edition; Bost et al. Immunolgogical Investigations, 17:577-586 (1988); and Owens et al. Journal of Immunological Methods, 168:149-165 (1994). *See*, Paper No. 20060519, pages 4-6, comments 7-8. Applicants respectfully disagree and traverse this rejection.

As a preliminary matter, it is not clear to Applicants if the Patent Office considered all arguments presented in Applicants' response dated March 20, 2006 regarding the rejection of claims 25-48 under 35 U.S.C. § 103(a). A brief summary is provided below. Applicants apologize if the Patent Office has already considered these issues.

Applicants have amended claims 25, 37, and 48 to recite the functional parameter "wherein said antibody or antibody fragment is useful for detecting or treating cancer." Since this use is not taught in the art cited by the Patent Office, in particular the EST disclosed in EMBL accession number AL035289, Applicants respectfully submit that these amendments obviate the Patent Office rejections.

Indeed, Applicants respectfully note that in order for a rejection under 35 U.S.C. § 103(a) to be valid, three criteria must be met (*See,* M.P.E.P. 706.02(j)):

a) there must be some suggestions or motivation to modify or to combine reference teachings;
b) there must be a reasonable expectation of success; and
c) the prior art reference (or references when combined) must teach or suggest all the claim limitations

(emphasis added).

Applicants respectfully submit that Campell (ed.), Monoclonal Antibody Technology, 1985; 2nd Edition; Bost et al. Immunolgogical Investigations, 17:577-586 (1988); and

Owens et al. Journal of Immunological Methods, 168:149-165 (1994) do not disclose the present invention and therefore there would be no motivation or suggestion to use their teachings, alone or in combination with any other reference, to obtain the present invention. Furthermore, as discussed above, EMBL accession number AL035289 discloses a single, partial sequence encoding a hypothetical protein wherein no polypeptide function or activity is disclosed or suggested. The fact that "antibodies are powerful immunochemical tools," as stated by the Patent Office on Paper No. 20060519, page 5, comment 7, would not motivate one of skill in the art to place the partial cDNA into an expression vector, transfect the partial cDNA in a suitable host cell, purify the partial polypeptide, generate antibodies from a partial polypeptide, and then screen the generated antibodies for use in diagnosing or treating cancer. Indeed, it is unlikely that one of skill in the art would be motivated to pursue a research plan ranging from several months to years based on the disclosure of a partial, hypothetical protein where no function or activity is disclosed or suggested solely because antibodies are powerful therapeutic tools.

Moreover, the skilled artisan would have no reasonable expectation of success using the single, partial sequence encoding a hypothetical protein disclosed EMBL accession number AL035289 in generating antibodies useful for diagnosing or treating cancer, as no function or activity is disclosed or suggested for the partial polypeptide. As such, the combination of EMBL accession number AL035289 and of Campell (ed.), Monoclonal Antibody Technology, 1985; 2nd Edition; Bost et al. Immunolgogical Investigations, 17:577-586 (1988); and Owens et al. Journal of Immunological Methods, 168:149-165 (1994) does not teach or suggest any, much less all, the present functional parameters of the invention. Therefore, the present invention is not obvious over the combination of references of the prior art. Applicants therefore respectfully request that the rejection of claims 25-48 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

IV. Conclusion

Applicants respectfully request that the above-made amendments and remarks be entered and made of record in the present application. The Patent Office is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

If there are any fees, not already accounted for, due in connection with the filing of this paper, please charge such fees to our Deposit Account No. 08-3425.

Dated: August 31, 2006

Respectfully submitted,

By _____

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